Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Joan H. Lefkow	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	03 C 5455	DATE	1/9/2004
CASE TITLE	Teva Pharmaceuticals USA, Inc. vs. Abbott Laboratories		

MOTION: [In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] Enter Memorandum Opinion and Order. The Court finds that an "actual controversy" exists between Teva and Abbott. Thus, this Court has subject matter jurisdiction. Defendant's motion to dismiss [18-1] is denied. Status hearing is set on 2/3/04 at 9:30 a.m. for scheduling conference.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		4 number of notices	Document Number
	No notices required.			
✓	Notices mailed by judge's staff.		date docketed	
	Notified counsel by telephone.		docketing deputy initials	34
	Docketing to mail notices.			
	Mail AO 450 form.		1/9/2004 date mailed notice	
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MD	courtroom deputy's initials	U.S. DISTRICT COURT CLERK 04 JAN 12 PM 7:52 FILED-EDT 10 Date/time received in central Clerk's Office	MD mailing deputy initials	

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

TEVA PHARMACEUTICALS USA, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 03 C 5455**
	)	**Judge Joan H. Lefkow**
ABBOTT LABORATORIES	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff, Teva Pharmaceuticals USA, Inc. ("Teva"), filed this action seeking a declaratory judgment that United States Patent Nos. 5,844,105 ("the '105 patent"), 5,945,405 ("the '405 patent"), and 5,858,986 ("the '986 patent") held by defendant, Abbott Laboratories ("Abbott"), are invalid and would not be infringed if Teva commercially marketed a generic version of Abbott's antibiotic BIAXIN. Before the court is Abbott's Motion to Dismiss for Lack of Subject Matter Jurisdiction, claiming that no case or controversy existed at the time Teva filed its suit. For the reasons stated below, Abbott's motion is denied.

I. Facts

Abbott is the exclusive licensee of United States Patent No. 4,331,803 ("the '803 patent"), a compound patent relating to clarithromycin, the active ingredient in Abbott's antibiotic BIAXIN. The '803 patent expires on May 23, 2005. In addition to the compound patent, Abbott is the current holder of the '105 patent, the '405 patent, and the '986 patent, all of

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which relate to crystal forms of clarithromycin. Abbott is also the current holder of Canadian Patent 2,261,732 ("the '732 patent"), which relates to BIAXIN products marketed in Canada.

On June 18, 2002, Novopharm Limited ("Novopharm"), a Canadian affiliate of Teva, served a "Notice of Allegation"[1] on Abbott and its Canadian Subsidiary, Abbott Laboratories Limited,[2] pertaining to an Abbreviated New Drug Submission ("ANDS") filed by Novopharm seeking regulatory approval to market a generic version of BIAXIN in Canada. In the Notice of Allegation, Novopharm asserted that the '732 patent was invalid and that Novopharm's clarithromycin product would not infringe the '732 patent. In response to the Notice of Allegation, Abbott filed a "Regulatory Application" in the Federal Court of Canada seeking an order prohibiting the Canadian Minister of Health from issuing a Notice of Compliance ("NOC") to Novopharm until the '732 patent expires.[3] Abbott has also filed Regulatory Applications against four other generic manufacturers who have challenged the '732 patent. On October 14, 2003, Novopharm agreed to withdraw its Notice of Allegation, and Abbott in turn agreed to discontinue its Regulatory Application.

On December 17, 2002, Teva submitted an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to

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[1]Any drug manufacturer who seeks to market a generic version of a patented drug in Canada must file an Abbreviated New Drug Submission ("ANDS") with the Minister of National Health and Welfare. The ANDS must be supported by an allegation asserting that the listed drug patent would not be infringed if the applicant's submission were granted and explaining the basis for the assertion. A notice of such allegation must be served on the holder of the patent. *See Eli Lilly & Co. et al.* v. *Apotex Inc. et al.* (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 3-5.

[2]For purposes of discussion regarding the Canadian proceedings, Abbott and Abbott Laboratories Limited are referred to as "Abbott."

[3]Under Canadian law, when an innovator company like Abbott receives a Notice of Allegation, it must commence an application for prohibition ("Regulatory Application") with 45 days, or the Minister of Health will issue an NOC to the generic manufacturer. An NOC is a prerequisite for marketing drugs. *See Eli Lilly & Co. et al.* v. *Apotex Inc. et al.* (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 3-5.

market a generic version of BIAXIN in the United States. On August 6, 2003, the same day Teva filed the present action, Teva sent a letter informing Abbott of the lawsuit and asking Abbott to provide a covenant not to sue. Abbott has refused to provide Teva with a covenant not to sue.

On three other occasions, Abbott has sued or maintained suit against Teva or its affiliate Novopharm for patent infringement relating to other drugs for which Teva has filed ANDAs: (1) *Abbott Laboratories* v. *Novopharm Ltd.*, 00 CV 2141, 00 CV 5094, and 01 CV 1914 (N.D. Ill.), concerning fenofibrate; (2) *Abbott Laboratories, Fournier Industrie at Sante & Laboratories Fournier SA* v. *Teva Pharmaceutical Co., Inc.*, C.A. 02-1512 (D. Del.), concerning fenofibrate; and (3) *Knoll Pharmaceutical Co., Inc. and The John and Lois Arnold Family Ltd. Liab. P'Ship* v. *Teva Pharmaceuticals USA, Inc.*, 01 CV 1646 (N.D. Ill.), concerning vicoprofen.

II. Requirements for Jurisdiction Under the Declaratory Judgment Act

The Declaratory Judgment Act limits issuance of a declaratory judgment to cases of "actual controversy." 28 U.S.C. § 2201(a). If no actual controversy exists between the parties regarding the subject on which declaratory judgment is sought, the court lacks subject matter jurisdiction. *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 239-40 (1937); *Spectronics Corp.* v. *H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991). A declaratory judgment "may not be a medium for securing an advisory opinion in a controversy which has not arisen." *Coffman* v. *Breeze Corp.*, 323 U.S. 316, 324 (1945).

In declaratory judgment actions involving allegations of patent noninfringement, invalidity, or unenforceability, an "actual controversy" exists where there is both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity by the

declaratory plaintiff which could constitute infringement or concrete steps taken with the intent to conduct such activity. *Fina Research, S.A.* v. *Baroid Ltd.*, 141 F.3d 1479, 1481 (Fed. Cir. 1998). The declaratory plaintiff bears the burden to establish, by a preponderance of the evidence, that the two-part test for an actual controversy has been met. *See McNutt* v. *General Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936)("[T]he court may demand that the party alleging jurisdiction justify his allegations by a preponderance of evidence.").

A. Reasonable Apprehension of Infringement Suit

The first prong of the "actual controversy" test looks to whether the conduct of the patent holder created an objectively reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit. *Spectronics*, 940 F.2d at 634; *Fina Research*, 141 F.3d at 1481. To demonstrate a reasonable apprehension of suit, a declaratory plaintiff need not establish that the defendant has made an explicit threat. *Kos Pharms., Inc.* v. *Barr Labs, Inc.*, 242 F. Supp. 2d 311, 314 (S.D.N.Y. 2003). It must, however, demonstrate "conduct that rises to a level sufficient to indicate an intent [of the patentee] to enforce its patent, i.e. to initiate an infringement action." *EMC* v. *Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996). The subjective impressions of the plaintiff are insufficient to satisfy the requirement. Rather, the court must find objective facts indicating the intent of the patentee to enforce its patent, considering the totality of the circumstances at the time the complaint was filed. *Arrowhead*, 846 F.2d at 736.

Teva contends that it reasonably apprehends a patent infringement suit by Abbott based on three factors: (1) Abbott commenced proceedings in Canada under the *Patented Medicines (Notice of Compliance) Regulations* ("the *PM(NOC) Regulations*") against Novopharm, a Teva affiliate, in connection with Novopharm's attempt to obtain approval to market generic versions

of BIAXIN in Canada; (2) Abbott has refused to covenant that it will not enforce its patent rights against Teva; and, (3) Abbott has a history of patent enforcement against Teva concerning Teva's efforts to market generic versions of Abbott's brand name drugs. Abbott denies that these factors give Teva any reasonable apprehension of a patent infringement suit. The court is persuaded that, when considered together, the Canadian proceedings and Abbott's history of patent enforcement against Teva rise to a level sufficient to indicate an intent on the part of Abbott to enforce its patent against Teva. Thus, Teva apprehension of an infringement suit by Abbott if Teva attempts to market a generic version of BIAXIN is reasonable.

1. Canadian Proceedings

Courts are divided on whether suit or threat of suit in a foreign forum on a corresponding foreign patent is sufficient to satisfy the reasonable apprehension requirement. For example, in *Dr. Beck & Co. G.m.b.H.* v. *General Electric Co.*, 210 F. Supp. 86, 92 (S.D.N.Y. 1962), *aff'd*, 317 F.2d 538 (2d Cir. 1963), the court held that the threat of suit for infringement of a United States patent cannot be inferred from the actual fact of suit on a corresponding foreign patent. The court reasoned that, because "a patent is co-extensive with the borders of sovereignty which granted it . . . infringement thereof cannot be predicated on acts consummated in a foreign country." *Id.*; *see also Gates Energy Products* v. *Yuasa Battery Co.*, 599 F. Supp. 368, 374 (D. Colo. 1983)(same). Other courts have held to the contrary. *See, e.g.*, *Electro Med. Sys. S.A.* v. *Cooper Lasersonics, Inc.*, 227 U.S.P.Q. 564, 565-66 (N.D. Ill. 1985)(the existence of prior infringement suits in foreign forums based on corresponding foreign patents and against plaintiff's allegedly infringing products is sufficient to create a reasonable apprehension of identical suits in the United States); *Ethicon, Inc.* v. *American Cyanamid Co.*, 369 F. Supp. 934,

937 (D.N.J. 1973)(suit on foreign counterpart patent is a sufficient threat). This court believes that the better view is that foreign litigation, while not dispositive of a reasonable apprehension of suit in the United States, is one factor to be considered in the analysis. *See Hakuto Corp., Ltd. v. Emhart Industries, Inc.*, 88 C 3659, 1989 WL 24118, at *3 (N.D. Ill. 1989)(holding that the threat of an infringement suit in Japan may not be dispositive, but is evidence of a patentee's willingness to employ litigation to enforce its patent rights).

Abbott argues, however, that the Canadian proceedings between Abbott and Novopharm are "simply not the type of litigation on foreign patents that [have] been deemed by some courts to be one of the many factors relevant to the reasonable apprehension analysis," because the Canadian proceedings are "actually . . . regulatory proceeding[s]." (Def. Memo. in Support of Mot. to Dismiss, at 12.) Abbott emphasizes that Novopharm, not Abbott, initiated the Canadian proceedings by filing a Notice of Application, which "requir[ed] Abbott to file the [Regulatory Application] within 45 days." (*Id.*) In contrast, Teva contends that the Canadian proceedings are "in every real sense a patent infringement suit" and is "precisely the type of controversy that courts have found give rise to a reasonable apprehension of suit." (Pl. Memo. in Opp'n to Mot. for Summ. J., at 3.)

The Canadian Federal Court of Appeal has explained the main features of the *PM(NOC) Regulations*, which govern the Canadian proceedings between Abbott and Novopharm, as follows:

> The Minister of National Health and Welfare ("the Minister") is responsible, under the *Food and Drug Regulations*, for the issuance of "notices of compliance" (hereinafter "NOC") attesting to the health, safety, and efficacy of drugs. An NOC is a prerequisite for marketing drugs. The drug manufacturer who holds or is licensed under subsisting patents is invited to file a patent list with the Minister indicating each of the drugs for

> which it already holds an NOC. From that point on, any other manufacturer who applies for an NOC in respect to the same drug, must support its new drug submission (hereinafter "NDS") by an allegation asserting that the listed drug patent would not be infringed if its application were granted, and explaining the basis for the assertion. A notice of such allegation must be served on the holder of the patent. Within 45 days of service of the allegation, the holder of the patent who wishes to dispute the justification of the allegation must seek an order from the Federal Court prohibiting the Minister from issuing the NOC applied for, and the Court will issue the order unless it finds the allegation is justified. An NDS for a listed medicine must be left in abeyance until the expiration of the time given to the patent-holder to respond and, if proceedings in prohibition are commenced, until they are dismissed or another 30 months expires. However, in the absence of proceedings, the Minister is directed to process the application and, unless there is any concern for public health or safety, will issue the NOC requested.

Eli Lilly & Co. et al. v. *Apotex Inc. et al.* (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 3. The Federal Court of Appeal has emphasized that the prohibition proceedings launched by the patentee "should not be likened to actions for determining validity or infringement but are of the nature of proceedings in judicial review, to be held expeditiously, whose aim is to determine whether the Minister is free to issue the [NOC] requested. Their scope is confined to administrative purposes." *Id.* at 5-6; *see also Pharmacia Inc.* v. *Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209 (F.C.A.) at 217 ("If the Governor in Council had intended by these regulations to provide for a final determination of the issues of validity or infringement, a determination which would be binding on all private parties, it surely would have said so. . . . If a full trial of validity or infringement issues is required this can be obtained in the usual way by commencing an action."). Thus, Abbott is correct that Canadian proceedings under the Regulations do not constitute a "patent infringement action."

Nevertheless, the Canadian proceedings are relevant to the reasonable apprehension analysis. Abbott was not required to file a Regulatory Application in response to Novopharm's

Notice of Allegation. If it had not done so, the Minister of Health would have issued a NOC to Novopharm, absent any concerns for public health or safety, and Novopharm would have been free to market its generic version of BIAXIN in Canada. By filing a Regulatory Application, Abbott initiated proceedings to prevent Novopharm from marketing a generic version of BIAXIN. *See Merck Frosst Canada Inc.* v. *Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (F.C.A.) at 319 (The party filing a Regulatory Application is "the initiator of the proceedings."). Abbott has also filed Regulatory Applications against four other generic manufacturers challenging the '732 patent. The *Regulatory Impact Statement* that was issued when the *PM(NOC) Regulations* were enacted states that proceedings under the Regulations are "designed to prevent patent infringement." (Mayo Decl., at 2, *citing Canadian Gazette Part II*, Vol. 127, No. 6, at 1389 (1993)). The *PM(NOC) Regulations* allow a patentee to "contest the allegation of non-infringement or invalidity. This provides the [patentee] with the opportunity to seek an order before the courts prohibiting the Minister of Health from issuing the NOC and allows the courts to determine the issue of that patent's application to the second or subsequent entry manufacturer's product." *Canadian Gazette Part II*, Vol. 133, No. 21, at 2357. The Canadian Proceedings clearly demonstrate that Abbott will not stand quietly by while manufacturers attempt to bring generic versions of its products to market, and are therefore relevant to the reasonable apprehension analysis.[4]

[4]Abbott argues that, because Novopharm withdrew of its Notice of Allegation against Abbott, Teva's reasonable apprehension of suit "cannot even arguably be premised on the Canadian regulatory proceeding now that it has been terminated." (Def. Reply Memo in Supp. of Mot. to Dismiss, at 3-4.) However, Abbott's initial filing of a Regulatory Application against Novopharm indicated its belief that Novopharm's product infringes Abbott's patent and indicated Abbott's intention to enforce that patent. Novopharm's withdrawal of its Notice of Allegation in no way undermines that conclusion. Thus, the Canadian proceedings remain relevant to the reasonable apprehension analysis.

2. Abbott's Refusal to Provide a Covenant Not to Sue

Teva argues that Abbott's refusal to provide a covenant not to enforce its patent rights against Teva is a relevant factor in Teva's reasonable apprehension of suit. However, Teva requested such a covenant on the same day that it filed the present action. "The presence or absence of jurisdiction must be determined on the facts existing *at the time the complaint under consideration was filed*." *Arrowhead*, 846 F.2d at 734 n.2 (emphasis added). Abbott's refusal to provide a covenant not to enforce its patent rights against Teva cannot have created a reasonable apprehension of suit *at the time the complaint was filed*, because Abbott had not yet refused to provide a covenant. Thus, Abbott's refusal is not relevant to the reasonable apprehension analysis.

3. Previous Litigation Between the Parties

Abbott admits that "a history of prior litigation may be a relevant factor" in evaluating the reasonableness of a party's apprehension of suit. (Def. Memo. in Supp. of Mot. to Dismiss, at 10.) However, Abbott contends that in order for prior litigation to be a relevant factor, the prior litigation must concern "the same or similar patents and products to those at issue in the declaratory judgment action." (Def. Reply in Supp. of Mot. to Dismiss, at 9.) Abbott contends that its prior litigation with Teva and its affiliates does not create a reasonable apprehension of suit because the prior suits did not concern any BIAXIN-related patent. The court disagrees.

Three times in the past three years, Abbott has sued or maintained suit against Teva or its affiliate Novopharm for patent infringement relating to other drugs for which Teva has filed ANDAs. These suits support Teva's reasonable apprehension that Abbott will challenge Teva's attempts to market a generic version of BIAXIN. *See Dr. Reddy's Laboratories, Ltd.* v.

AaiPharma Inc., 01cv10102(LAP), 2002 WL 31059289, at *8 (S.D.N.Y. 2002)(holding that three previous suits filed by defendant against plaintiff involving the manufacture of generic versions of Prozac were "additional support for [plaintiff's] reasonable apprehension of an infringement suit" regarding its attempt to manufacture a generic version of Prilosec); *Premo Pharmaceutical Laboratories* v. *Pfizer, Inc.*, 212 U.S.P.Q. 681, 682 (S.D.N.Y. 1981)(holding that two previous suits filed by defendant against plaintiff involving its attempts to manufacture generic products of defendant's products "have created the reasonable apprehension that [defendant] will challenge all [plaintiff] attempts to market drugs that resemble [defendant's] products[5]).

Most of the cases that Abbott cites in support of the proposition that prior unrelated litigation is always irrelevant to a reasonable apprehension analysis are inapposite here. In both *Indium Corp. of America* v. *Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985), and *Premo Pharmaceutical Laboratories* v. *Pfizer, Inc.*, 465 F. Supp. 1281, 1283-84 (S.D.N.Y. 1979), the prior litigation held to be irrelevant was between the defendant and parties unrelated to the plaintiff. In *International Harvester Co.* v. *Deere & Co.*, 623 F.2d 1207, 1212 (7th Cir. 1980), the court actually held that pending litigation between parties involving an unrelated patent "is of some relevance. It indicates that under certain circumstances, [defendant] will pursue patent litigation to defend against what it perceives as infringement of its patents." In *Kos Pharmaceuticals, Inc.* v. *Barr Labs, Inc.*, 242 F. Supp. 2d 311, 315 (S.D.N.Y. 2003), the court found that the prior litigation between the parties did involve the same technology at issue in the

[5]Abbott mistakenly attempts to distinguish *Premo* from the instant case by stating that the prior suits involved the same product at issue in the declaratory judgment action. In fact, the previous suits involved different products. *See Premo*, 212 U.S.P.Q. at 682 n. 2.

declaratory judgment action. Thus, the court did not rule on the issue of whether previous unrelated litigation was relevant. In *O'Hagins, Inc.* v. *M5 Steel Mfg., Inc.*, 276 F. Supp. 2d 1020, 1025 (N.D. Cal. 2003), the "prior litigation" held to be irrelevant was a single trademark infringement suit eight years prior to the declaratory judgment action.

Abbott cites only two cases that support its contention that prior unrelated litigation is always irrelevant to a reasonable apprehension analysis, *Moore U.S.A., Inc.* v. *The Standard Register Co.*, 2001 WL 34076423 (W.D.N.Y. Aug 28, 2001), and *Ryko Mnfct. Co.* v. *Delta Services and Equipment Corp.*, 28 U.S.P.Q.2d 1558 (E.D.La.1993). This court is not bound by the holdings in these cases and finds them unpersuasive when applied to the facts of this case.

In combination with the Canadian proceedings, Abbott's recent history of enforcement of its patent rights against Teva and its affiliates is sufficient to create a reasonable apprehension that Abbott will initiate a patent infringement suit against Teva if Teva attempts to market a generic version of BIAXIN. To deny that a reasonable apprehension exists in this situation is to "ignore the realities of business life." *Muller* v. *Olin Mathieson Chemical Corp.*, 404 F.2d 501, 505, 160 U.S.P.Q. 1, 3-4 (2d Cir. 1968) *citing* 6A Moore's Federal Practice, P57.20 at 3121 (2d ed. 1966).

B. Present Activity Which Could Constitute Infringement or Concrete Steps Taken With the Intent to Conduct Such Activity

The second prong of the "actual controversy" test looks to whether the declaratory plaintiff has engaged in activity which could constitute infringement or has taken concrete steps with the intent to conduct such activity. *Fina Research*, 141 F.3d at 1481. The court finds that,

by filing an ANDA for clarithromycin, Teva committed a technical act of infringement sufficient to satisfy the second prong of the "actual controversy"test.

The Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act," provides in relevant part

> (2) It shall be an act of infringement to submit -
> (A) an application under Section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . .
> If the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A). Teva filed an ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The ANDA was for a drug claimed in a patent. The purpose of Teva's submission was to obtain approval under the FDCA to engage in the manufacture and sale of a generic version of Abbott's drug prior to the expiration of Abbott's patent. Thus, according to the literal language of § 271(e)(2)(A), Teva's filing of an ANDA constituted an infringement of Abbott's patent. *See Glaxo Group Ltd.* v. *Apotex, Inc.*, 272 F. Supp.2d 772 (N.D. Ill. 2003).

Abbott contends, however, that § 271(e)(2)(A) does not provide a basis for a finding of actual infringement in this case because the patents at issue were not listed in the FDA's "Orange Book" and therefore were not certified in Teva's ANDA. Resolution of this issue requires an examination of the structure and purpose of the Hatch-Waxman Act.

In *Eli Lilly and Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990), the Supreme Court explained that the Hatch-Waxman Act was passed to respond to certain distortions of the seventeen year patent period. *See* 35 U.S.C. § 154 (granting to the patentee, for the term of seventeen years, the right to exclude others from making, using, or selling the invention in the

United States). Prior to the Hatch-Waxman Act, generic drug manufacturers were required to file a New Drug Application ("NDA") to market a generic version of a drug already claimed in a patent. The generic manufacturer was required to provide its own independent safety and efficacy data in the NDA. However, the Federal Circuit held in *Roche Products, Inc.* v. *Bolar Pharmaceutical Co.*, 733 F.2d 858, *cert. denied*, 469 U.S. 856 (1984), that the manufacture, use, or sale of a patented invention constituted an act of infringement even if it was for the sole purpose of conducting tests and developing information necessary to obtain regulatory approval. Thus, those who planned to market a generic version of a patented drug could not conduct tests or develop information until after the expiration of the entire patent term, creating a "*de facto* monopoly" for the patentee that "would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term." *Eli Lilly*, 496 U.S. at 670.

The Hatch-Waxman Act was created to deal with this *de facto* extension of the patent term by enabling generic drugs to be marketed more cheaply and quickly. *Id.* at 676. First, in response to *Roche*, Congress added subsection (e)(1) to 35 U.S.C. § 271, which provides that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under federal law which regulates the manufacture, use, or sale of drugs. . . ." Section 271(e)(1) allowed generic manufacturers, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval. *Eli Lilly*, 496 U.S. at 671. Second, Congress amended § 505 of the FDCA, 21 U.S.C. § 355, to authorize the filing and approval of ANDAs, which

would substantially shorten the time and effort it took a generic manufacturer to obtain market approval. *Id.* at 676. An ANDA may be filed for a generic drug that is the same as a "pioneer drug" previously approved or that differs from the pioneer drug in specified ways. *See* 21 U.S.C. § 355(j)(2)(A) and (j)(2)(C). The ANDA applicant can substitute bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full NDA. *Eli Lilly*, 496 U.S. at 676 (comparing 21 U.S.C. § (j)(2)(A)(iv) with § 355(b)(1)).

The Supreme Court explained, however, that in addition to shortening the time and effort necessary to obtain market approval, the Hatch-Waxman Act also sought to guard against infringement of patents relating to pioneer drugs. *Id.* NDA applicants are required to file with the FDA the number and expiration date of any patents that claim the approved drug or the approved use of the drug. The FDA then lists the patent information in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book"). 21 U.S.C. § 355(b)(1). ANDA applicants seeking approval to market a generic form of a pioneer drug are required to include in their ANDAs one of four "certifications" with respect to each patent named in the previously filed NDA application for the pioneer drug: "(I) that such patent information has not been filed, (II) that such patent has expired, (III) the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. . . ."("a paragraph IV certification")." 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

ANDAs containing a paragraph IV certification may become effective immediately if the patent owner does not initiate a lawsuit for infringement within 45 days of receiving notice of the certification. Thus, an act of infringement had to be created for ANDA applicants "to create case

or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo, Inc.* v. *Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Congress did this by adding § 271(e)(2)(A), which created an "artificial act of infringement" that consists of submitting an ANDA if the purpose of such submission is to obtain approval to engage in the commercial manufacture, use, or sale of a drug claimed in a patent before the expiration of the patent, such as an ANDA containing a paragraph IV certification. *Glaxo*, 272 F. Supp.2d at 776 (citing *Eli Lilly*, 496 U.S. at 678).

The Hatch-Waxman Act struck a balance between the interests of innovative drug manufacturers and the interests of generic drug manufacturers. "On the one hand, the manufacture, use or sale of a patented drug is not an act of infringement, to the extent it is necessary for the preparation and submission of an ANDA. On the other hand, once it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to the expiration of the patent, the patent owner can seek to prevent approval of the ANDA by bringing a patent infringement suit." *Bristol-Myers Squibb Co.* v. *Royce Laboratories, Inc.*, 69 F.3d 1130, 1132 (Fed. Cir. 1995).

Complicating matters in the instant case, however, is the fact that, at the time the Hatch-Waxman Act was passed (1984), the FDCA had a separate section prescribing the regulatory process for approval to market antibiotic drugs. 21 U.S.C. § 357. Thus, § 271(e)(2), which created the artificial act of infringement for seeking the approval of an ANDA under § 505(j) to obtain approval to make, use, or sell the generic drug prior to the expiration of the patent on the pioneer drug, did not apply to antibiotics, because manufacturers seeking regulatory approval to market generic versions of patented antibiotics did not seek approval under § 505(j). *Glaxo*,

272 F. Supp.2d at 777. However, § 271(e)(1), exempting from infringement the manufacture, use or sale of a drug for the purposes of developing and submitting information under a "federal law which regulates the manufacture, use, and sale of drugs," did apply to antibiotics. *Id.*

In 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (the "Modernization Act"), which repealed 21 U.S.C. § 357, the old regulatory process for the approval of antibiotic drugs. Pub. L. No. 105-115, 111 Stat 2296 (1997). As a result, generic manufacturers of antibiotics must now apply for ANDAs under § 505(j). However, the Modernization Act exempts antibiotic drug manufacturers who had filed previously under § 357 ("old antibiotics') from Orange Book listing and also exempts ANDA applicants for generic versions of old antibiotics from the certification requirements under § 355(j)(2)(A)(vii). *Glaxo*, 272 F. Supp.2d at 777; *see* 21 U.S.C.A. § 355 Note (d)(2)(stating that § 355(j)(2)(a)(vii) "shall not apply to any application for marketing in which the drug that is the subject of the application contains an antibiotic drug and the antibiotic drug was the subject of any application for marketing received by the Secretary of Health and Human Services under section 507 of [the FDCA] (21 U.S.C. 357) before the date of enactment of this Act.).

Because clarithromycin is an "old antibiotic," the patents claiming it are not listed in the Orange Book. Therefore, even though clarithromycin was claimed in various patents and Teva knew that when it filed its ANDA, Teva was not required to provide a certification under § 355(j)(2)(A)(vii). In particular, despite the fact that it intended to market 250 and 500 mg tablets of clarithromycin before the expiration of the '105 patent, the '405 patent, and the '986 patent, Teva was not required to file a paragraph IV certification that these patents were invalid or would not be infringed by the use, manufacture, or sale of the new generic drug. For these

reasons, Abbott contends that § 271(e)(2)(A), which created the "artificial act of infringement" for filing an ANDA, does not apply to Teva's ANDA.

Abbott relies on *Abbott Laboratories* v. *Zenith Laboratories, Inc.*, 94 C 6792, 1995 WL 117984 (N.D. Ill. Mar. 16, 1995). In *Zenith*, the court held that "an action for patent infringement brought pursuant to § 271(e)(2)(A) cannot be premised on a patent not included in a NDA filed pursuant to § 355(b)(1), and thus not connected with a drug listed" in the Orange Book. 1995 WL 117984, at *10. The court reasoned that the "language of § 271(e)(2)(A) clearly implicates the procedures outlined in § 355(j) [of the FDCA]." *Id.* The court then pointed out that § 355(j)(2)(A)(vii) requires "a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims a use for *such listed drug referred to in clause (i)* or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and *for which information is required to be filed under subsection (b) or (c) of this section . . .*" *Id.* (emphasis in original). Because the plaintiff neglected to file an NDA pursuant to § 355(b)(1), the patent at issue was never listed in the Orange Book. Therefore, the defendant was not required to include a certification for the patent in its ANDA.

However, the *Zenith* court did not clearly explain why the plaintiff's failure to include a certification in its ANDA precluded the plaintiff from maintaining an infringement suit pursuant to § 271(e)(2)(A). The language of § 271(e)(2)(A) does not require that the ANDA contain a certification to constitute an act of infringement. It only requires that the application be filed under § 355(j).

Apparently, the court relied on dicta from *Eli Lilly* to reach its holding. In *Eli Lilly*, the Court explained that if an ANDA includes a paragraph IV certification, the FDCA requires the

ANDA applicant to give notice to the holder of the patent that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the generic drug before the expiration of the patent which claims the pioneer drug. 496 U.S. at 677 (citing 21 U.S.C. § 355(j)(2)(B)(ii)). The patent owner is then given 45 days from the date he receives notice to initiate a patent infringement suit. *Id.* (citing 21 U.S.C. § 355(j)(2)(B)(iii)). If the patent owner does not bring a patent infringement suit, then the FDA can approve the ANDA effective immediately. *Id.* If the patent owner brings a suit, then the FDA approval does not become effective until a court rules that the patent is not infringed or until expiration of 30 months, whichever comes first. *Id.* The Court explained

> This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new 35 U.S.C. § 271(e)(1) imposed with regard to the use of his patented invention only for the purpose of obtaining premarketing approval. Thus, an act of infringement had to be created for these ANDA . . . proceedings. That is what is achieved by § 271(e)(2)–the creation of a highly artificial act infringement that consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use or sale of the new drug . . . [would] violate the relevant patent.

Id. at 678.

This is a persuasive explanation of *why* Congress passed § 271(e)(2), but it does not follow that Congress therefore intended to limit the artificial act of infringement created by § 271(e)(2) to ANDAs containing paragraph IV certifications. If Congress had so intended, it could have easily done so. The provision might have read, for example, "It shall be an act of infringement to submit an application containing a certification described in § 355(j)(2)(a)(vii)(IV)." Instead, the provision makes it an act of infringement to submit "an

application under Section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . . If the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2)(A).

Furthermore, as this court pointed out in *Glaxo*, holding that § 271(e)(2)(A) applies only when the ADNA includes a paragraph IV certification would create a disequilibrium between holders of patents on old antibiotics and manufacturers seeking to market generic versions of those old antibiotics. Generic manufacturers of "old antibiotics" would be able to take advantage of § 271(e)(1) to manufacture, use, or sell a drug if done solely for the submission of an ANDA without violating the pioneer patent. However, the patent holder of the old antibiotic would not be permitted to maintain a suit under § 271(e)(2)(A) against the generic manufacturer that submitted an ANDA until the marketing of the generic drug was imminent. As mentioned above, this disequilibrium existed before the Modernization Act was passed, but it seems unlikely that Congress intended to maintain the disequilibrium with the passage of the Modernization Act.

For these reasons, the court declines to adopt the reasoning set forth in *Zenith* and relies instead on the plain language of § 271(e)(2), which provides that the submission of an ANDA under § 355(j) is an act of infringement if the purpose is to obtain approval to engage in the commercial manufacture, use, or sale of a drug claimed in a patent before the expiration of the patent. This is what Teva did. Therefore, Teva's submission of an ANDA constituted an act of

infringement sufficient to satisfy the second prong of the "actual controversy" test set forth in *Fina Research*, 141 F.3d at 1481.

CONCLUSION

For the reasons stated above, the court finds that an "actual controversy" exists between Teva and Abbott. Thus, this court has subject matter jurisdiction. Abbott's Motion to Dismiss is denied (#18).

ENTER: _____
JOAN HUMPHREY LEFKOW
United States District Judge

Dated: January 9, 2004